IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
WESTERN DIVISION

Jennifer L. Burdine, et al.,

Plaintiff

v.

Stryker Corporation, et al.,

Defendant

Case No. 3:10CV1334

ORDER

This is a product liability suit in which the plaintiff Jennifer L. Burdine claims that she suffered permanent damage to her right shoulder in 2004 following post-operative treatment with a pain pump manufactured by the defendant Stryker Corporation. In essence, she contends that Stryker promoted use of the pump under conditions for which the FDA had not granted permission for its use—namely, through administration of an excessive volume of pain medication.

Plaintiff seeks, *inter alia*, punitive damages. Pending is defendant's Rule 12(b)(6) motion to dismiss that claim. [Doc. 9]. For the reasons that follow, I deny the motion without reaching the substantive merits of defendant's arguments and without prejudice.

Ohio law strictly and severely limits a plaintiff's ability to recover punitive damages in cases involving drugs and medical devices. Revised Code § 2307.80 provides in pertinent part:

> (A) Subject to divisions (C) and (D) of this section, punitive or exemplary damages shall not be awarded against a manufacturer or supplier in question in connection

> with a product liability claim unless the claimant establishes, by clear and convincing evidence, that harm for which the claimant is entitled to recover compensatory damages in accordance with section 2307.73 or 2307.78 of the Revised Code was the result of misconduct of the manufacturer or supplier in question that manifested a flagrant disregard of the safety of persons who might be harmed by the product in question. The fact by itself that a product is defective does not establish a flagrant disregard of the safety of persons who might be harmed by that product.
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> * * * * *
>
> (C)(1) Except as provided in division (C)(2) of this section, if a claimant alleges in a product liability claim that a drug or device caused harm to the claimant, the manufacturer of the drug or device shall not be liable for punitive or exemplary damages in connection with that product liability claim if the drug or device that allegedly caused the harm satisfies either of the following:
>
> > (a) It was manufactured and labeled in relevant and material respects in accordance with the terms of an approval or license issued by the federal food and drug administration. . . .
>
> * * * * *
>
> (2) Division (C)(1) of this section does not apply if the claimant establishes, by a preponderance of the evidence, that the manufacturer fraudulently and in violation of applicable regulations of the food and drug administration withheld from the food and drug administration information known to be material and relevant to the harm that the claimant allegedly suffered or misrepresented to the food and drug administration information of that type.

As plaintiff argues, § 2307.80(C)(1)(a) creates an affirmative defense to a claim for punitive damages in a drug or medical device personal injury case. The defendant has the burden of pleading and proving that the drug or device "was manufactured and labeled in relevant and material respects in accordance with the terms of" FDA approval.

If a defendant fails to meet this burden, the plaintiff can, if the evidence supports such award, recover punitive damages.

If the defendant meets its burden of proof as to compliance with the manufacturing and labeling requirements consequent on FDA approval, the burden then shifts to the plaintiff to prove that the defendant "fraudulently . . . withheld. . . information known to be material and relevant to

the harm that the claimant allegedly suffered or misrepresented to the food and drug administration information of that type."

The case gets to that stage—and concurrently consideration of defendant's argument that plaintiff's "fraud on the FDA" contention is pre-empted—only after the defendant has met its initial burden of proof regarding manufacturing and labeling compliance.

At this point, defendant has asserted such compliance in (and, indeed, submitted some proof with) its brief in support of its motion to dismiss. But it has not answered plaintiff's complaint and thereby put the issue of compliance in play. Nor has it produced evidence of compliance with regard to either proper manufacturing or labeling. Nor has plaintiff had discovery responsive to any such evidence.

I thus agree with my colleague Judge John Adams that it is premature to consider the various arguments that defendant makes in support of the current motion. *Mayle v. Styker Corp.*, 2010 WL 1170635, *3 n.2 (N.D. Ohio). This is so even if, as defendant contends, it has resolved (as Judge Adams thought it had not on the basis of what was before him, *id*., at *3) the issue of FDA approval. It is not mere approval, but rather *compliance* that potentially can relieve a defendant of liability for punitive damages.

At this point, the burden is not on plaintiff to allege fraud on the FDA, much less to do so with the particularity which Fed. R. Civ. P. 9(b) requires. While I have little doubt that defendant's answer will allege compliance under § 2307.80(C)(1)(a) as an affirmative defense, it can do so only in that pleading. Its effort to use Rule 12(b)(6) to by-pass that obligation and have me disregard the allocation of the burden of proof under § 2307.80(C)(1)(a) cannot succeed.

It is, therefore,

ORDERED THAT

1. Defendant's motion to dismiss (Doc. 9) be, and the same hereby is overruled without prejudice; and

2. Leave be, and the same hereby is granted to defendant to answer plaintiff's complaint on or before February 15, 2011.

So ordered.

s/James G. Carr
United States District Judge